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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,835

06/05/2006

Tor Kihlberg

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GE HEALTHCARE, INC.

IP DEPARTMENT 101 CARNEGIE CENTER

PRINCETON, NJ 08540-6231

EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

03/31/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/581,835	Applicant(s) KIHLEBERG ET AL.	
	Examiner MELISSA PERREIRA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 13-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claims and Previous Objections and Rejections Status

2. Claims 1-25 are pending. Claims 13-25 are withdrawn from consideration.
3. The rejection of claims 1-5 and 7 under 35 U.S.C. 103(a) as being unpatentable over Diksic et al. (*Int. J. Nucl. Med. Biol.* **1982**, 9, 283-285) in view of Suzuki et al. (EP0282703B1) and Shiba et al. (US 4,458,302) and in further view of Kihlberg et al. (US2004/0197257A1) is modified to include Gascard et al. (*J. Phys. E: Sci. Instrum.* **1982**, 15, p627-628).
4. The rejection of claims 1-12 under 35 U.S.C. 103(a) as being unpatentable over Kihlberg et al. (US 7,521,544B2) in view of Diksic et al. (*Int. J. Nucl. Med. Biol.* **1982**, 9, 283-285) is withdrawn as the applicants stated that the patent '544 and the instant invention were commonly owned at the time the invention was made in the remarks filed 3/11/11.
5. The rejection of claims 1-7 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,521,544 in view of Diksic et al. (*Int. J. Nucl. Med. Biol.* **1982**, 9, 283-285) is maintained.
6. The rejection of claims 8-12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-11 of copending Application No. 12/423,034 is maintained.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diksic et al. (*Int. J. Nucl. Med. Biol.* **1982**, 9, 283-285) in view of Suzuki et al. (EP0282703B1), Shiba et al. (US 4,458,302) and Gascard et al. (*J. Phys. E: Sci. Instrum.* **1982**, 15, p627-628) and in further view of Kihlberg et al. (US2004/0197257A1).

9. Diksic et al. (*Int. J. Nucl. Med. Biol.* **1982**, 9, 283-285) discloses the production of high specific activity (no-carrier-added) [^{11}C]phosgene wherein [^{11}C]carbon monoxide was mixed with research purity chlorine flowing at 10 ml/min. The mixture was irradiated with a u.v.-lamp, in a quartz spiral wound around the lamp, to generate $^{11}\text{COCl}_2$ which is collected in a reaction vessel after a period of time. The radiochemical yield is about 90% (p284, left column; p283, right column, especially experimental results; figure 1). The reaction apparatus for the production of [^{11}C]phosgene comprises a first and a second inlet for the introduction of [^{11}C]carbon monoxide and chlorine.

10. Diksic et al. does not disclose a high pressure reaction chamber comprising a concave mirror or stirring the reaction chamber.

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11. Suzuki et al. (EP0282703B1) discloses that UV radiation source which comprises a high pressure mercury vapor lamp, a concave mirror and a shutter which can be opened and closed. The radiant lights containing ultraviolet rays are emitted from the high pressure mercury lamp and are reflected by the concave mirror (column 4, lines 1-18).

12. Shiba et al. (US 4,458,302) discloses the use of concave mirrors for convergence of the light emitted from a Xe-Hg lamp (column 6, lines 3-10).

13. Gascard et al. (*J. Phys. E: Sci. Instrum.* **1982**, 15, p627-628) discloses a magnetically stirred UV-autoclave for gas-liquid reactions. It is important to provide an intense mixing of the gas-liquid system to keep the solubility equilibrium constant (abstract; p627, left column, first paragraph; p627, right column; figure 1).

14. At the time of the invention it would have been obvious to one skilled in the art to substitute the UV radiation source which comprises a high pressure mercury vapor lamp and a concave mirror of Suzuki et al. for the UV assembly of Diksic et al. as the substitution of similar/comparable devices is obvious, wherein the technique is applicable to the base device, to generate the desired effect, such as converging all of the UV light to provide for the efficacious generation of $^{11}\text{COCl}_2$. It would be advantageous to one skilled in the art to utilize the UV radiation source of Suzuki et al. comprising a concave mirror to converge all of the light emitted from the UV source for a more efficient labeling synthesis as none of the extraneous UV radiation is lost.

15. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize a stirring mechanism, such as that of Gascard et al. with the UV

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apparatus of the combined disclosures for the preparation of $^{11}\text{COCl}_2$ to properly mix the $[^{11}\text{C}]$ carbon monoxide and chlorine as Gascard et al. teaches that it is important to provide an intense mixing of the gas-liquid system to keep the solubility equilibrium constant.

16. Diksic et al. does not disclose using a $[^{11}\text{C},^{13}\text{C},^{14}\text{C}]$ carbon monoxide enriched gas-mixture prepared via the method of the instant claim 2.

17. Kihlberg et al. (US2004/0197257A1) discloses the production of $[^{11}\text{C},^{13}\text{C},^{14}\text{C}]$ carbon monoxide enriched gas-mixture for labeling synthesis via a.) providing carbon-isotope dioxide in a suitable carrier gas (i.e. nitrogen, etc.); b.) converting carbon-isotope dioxide to carbon-isotope monoxide by introducing said gas mixture in a reactor device; c.) trapping carbon-isotope monoxide in a carbon monoxide trapping device, wherein carbon-isotope monoxide is trapped but not said carrier gas; d.) releasing said trapped carbon-isotope monoxide from said trapping device in a well defined micro-plug, whereby a volume of carbon-isotope monoxide enriched gas-mixture is achieved (p2, [0018-0026]; claim 1).

18. Kihlberg et al. further teaches of the method of labeling synthesis wherein the method comprises a.) introducing the carbon-isotope monoxide (i.e. $[^{11}\text{C},^{13}\text{C},^{14}\text{C}]$ carbon monoxide) enriched gas-mixture into a reaction chamber, having a liquid reagent inlet and a labeling reactant inlet ($[^{11}\text{C},^{13}\text{C},^{14}\text{C}]$ carbon monoxide); b.) introducing, at high pressure, the liquid reagent; c.) waiting a predetermined time while the labeling synthesis occurs; d.) removing the labeled liquid reagent from the reaction chamber.

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The step of waiting a predetermined time may further comprise heating the reaction chamber such that the labeling synthesis is enhanced (p2, [0031-0037]).

19. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the [^{11}C , ^{13}C , ^{14}C]carbon monoxide enriched gas-mixture of Kihlberg et al. for the preparation of [^{11}C]phosgene of Diksic et al. as it provides for the advantage of nearly quantitative conversion of the carbon-isotope monoxide into labeled products and the resulting labeled compound is highly concentrated (Kihlberg et al. p1, [0010],[0012]).

20. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the high pressure reaction chamber for the labeling synthesis/preparation of [^{11}C]phosgene of Diksic et al. as the high pressures can increase reaction rates and minimize the amounts of reagents required (Kihlberg et al. p1, [0007]) and both disclosures are drawn to the method of labeling synthesis utilizing [^{11}C , ^{13}C , ^{14}C]carbon monoxide.

Response to Arguments

21. Applicant's arguments filed 3/11/11 have been fully considered but they are not persuasive.

22. Applicant asserts that applicants designed a system and developed a method that reduces reaction volumes and associated amounts of reactants, but is also produces [^{11}C]phosgene with a decay-corrected radiochemical yield of 70-85% and a surprisingly high radioactivity of 200GBq/micromol, which amounts to 200TBq/mmol. In addition, the claimed method significantly reduces isotopic dilution during the labeling

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synthesis to the point that it becomes negligible. These data and findings were presented by two of the named inventors, Oleksiy Itsenko and Tor Kihlber, on September 10, 2010 at the 2010 World Molecular Imaging Congress in Kyoto, Japan. A copy of the poster and an abstract, are provided.

23. First, Oleksiy Itsenko is not listed as an inventor of the instant application/invention. Tor Kihlberg, Tommy Ferm and Bengt Langstrom are listed as inventors of the instant invention.

24. The provided reference (3/11/11) poster of the 2010 World Molecular Imaging Congress in Kyoto, Japan is by others (O. Itsenko, G. Antoni and T. Kihlberg) and thus the inventorship of the instant invention contained within the provided reference is unclear.

25. The specification does not recite "produces [^{11}C]phosgene with a decay-corrected radiochemical yield of 70-85% and a surprisingly high radioactivity of 200GBq/micromol, which amounts to 200TBq/mmol" but recites th method for synthesizing [^{11}C]phosgene with high specific radioactivity.

26. Diksic et al. teaches of the radiochemical yield is about 90% and thus the radiochemical yield of 70-85% as stated by the applicant is not surprising.

27. Further, Kihlberg et al. teaches of the production of [^{11}C , ^{13}C , ^{14}C]carbon monoxide enriched gas-mixture for labeling synthesis.

28. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the [^{11}C , ^{13}C , ^{14}C]carbon monoxide enriched gas-mixture of Kihlberg et al. for the preparation of [^{11}C]phosgene of Diksic et al. as it provides for the advantage

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of nearly quantitative conversion of the carbon-isotope monoxide into labeled products and the resulting labeled compound is highly concentrated. Thus, [^{11}C , ^{13}C , ^{14}C]carbon monoxide enriched gas-mixture the reduces reaction volumes and significantly reduces isotopic dilution during the labeling synthesis.

Double Patenting

29. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,521,544 in view of Diksic et al. (*Int. J. Nucl. Med. Biol.* **1982**, 9, 283-285) because the method of labeling synthesis of the instant claims encompasses the method for labeling synthesis of 7,521,544 as they use the same UV reactor assembly, high pressure reaction chamber and carbon-isotope monoxide enriched gas-mixture prepared by the same method to label a reagent volume. U.S. Patent No. 7,521,544 does not disclose that the reagent volume to be labeled is phosgene via mixing carbon-isotope monoxide enriched gas-mixture with chlorine gas.

31. Diksic et al. discloses the preparation of [¹¹C]phosgene via mixing [¹¹C]carbon monoxide with research purity chlorine and irradiation with an u.v.-lamp apparatus. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the method of labeling synthesis of 7,521,544, such as the use of the [¹¹C, ¹³C, ¹⁴C]carbon monoxide enriched gas-mixture of 7,521,544 for the preparation of [¹¹C]phosgene of Diksic et al. as the resulting labeled compound is highly concentrated and the method of 7,521,544 provides for an enhanced radiochemical yield (7,521,544 column 4, lines 5-9; column 17, lines 56+; table 2).

32. Claims 8-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-11 of copending Application No. 12/423,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the system for labeling synthesis of the instant claims comprising a UV reactor assembly comprising a high pressure reaction chamber, UV lamp, motor, magnet, magnetic stirring bar, concave mirror, sapphire window, protective housing, etc. of the instant claims encompasses the system for labeling synthesis of application 12/423,034 as it comprises the same components. The high pressure reaction chamber of the instant claims has a first gas inlet and a second gas inlet while the high pressure reaction chamber of the copending application 12/423,034 has a liquid inlet and a gas inlet and it would have been obvious to one skilled in the art that the liquid inlet of the high pressure reaction chamber can be adapted for the intake of gas.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

33. Applicant's arguments filed 3/11/11 have been fully considered but they are not persuasive.

34. Applicant asserts that they will consider filing a terminal disclaimer to overcome the ODP rejections once the claims of the instant application are held to be otherwise allowable.

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35. The applicant has not filed a terminal disclaimer to overcome the ODP rejections and thus the rejections are maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

36. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

37. Claims 8,9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Shi et al. (US 6,284,050B1).

38. Shi et al. (US 6,284,050B1) teaches of an ultraviolet-assisted chemical vapor deposition system comprising a UV light source **(154)** (e.g. high pressure mercury arc lamp), an ultraviolet reflector **(158)** (e.g. parabolic surface) to uniformly illuminate the semiconductor wafer with all of the UV light reflected by the UV reflector, an optical window to transmit the ultraviolet light **(140)** (e.g. sapphire), optical shutter mounted directly below the window **(144)** and inlets **(128)** (figure 1, column 2, lines 12-23; column 3, lines, 40+; column 4).

Claim Rejections - 35 USC § 103

39. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

40. Claim 8,9,11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (EP0282703B1) in view of Shi et al. (US 6,284,050B1) and Shiba et al. (US 4,458,302) and in further view of Maag et al. (US 6,472,026B1) and Gadgil et al. (5,780,860).

41. Suzuki et al. (EP0282703B1) discloses that UV radiation source for treating photoresist materials (semiconductor wafer) with UV which comprises a high pressure mercury vapor lamp **(1)**, a concave mirror **(2)**, a shutter (window) **(3)** which can be opened and closed and an intake **(12)**. The radiant lights containing ultraviolet rays are emitted from the high pressure mercury lamp and are reflected by the concave mirror (column 3, lines 55+; column 4, lines 1-18).

42. Suzuki et al. does not disclose two inlets or a sapphire window.

43. Shi et al. (US 6,284,050B1) discloses an ultraviolet-assisted chemical vapor deposition system (CVD) to uniformly cover a semiconductor wafer surface with UV wherein the CVD system comprises a UV light source **(154)** (e.g. high pressure mercury arc lamp), an ultraviolet reflector **(158)** (e.g. parabolic surface) to uniformly illuminate the semiconductor wafer with all of the UV light reflected by the UV reflector, an optical window to transmit the ultraviolet light **(140)** (e.g. sapphire), optical shutter mounted directly below the window **(144)** and inlets **(128)** (figure 1, column 2, lines 12-23; column 3, lines, 40+; column 4).

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44. At the time of the invention it would have been obvious to one ordinarily skilled in the art to include multiple inlets and a sapphire window for the UV apparatus of Suzuki et al. as Shi et al. teaches of a comparable UV CVD system comprising two to four inlets and a sapphire window to transmit UV light. Both disclosures are drawn to the same utility, such as the use of a UV apparatus for the irradiation of a semiconductor wafer with UV light and the substitution of similar/comparable devices is obvious, wherein the technique is applicable to the base device, to generate the desired effect, such as irradiating the semiconductor wafer with UV light.

45. Suzuki et al. does not disclose that the concave mirror focuses the UV light.

46. Shiba et al. (US 4,458,302) discloses the use of concave mirrors for convergence of the light emitted from a Xe-Hg lamp (column 6, lines 3-10).

47. At the time of the invention it would have been obvious to one ordinarily skilled in the art that the concave mirrors of the UV radiation source of Suzuki et al. focuses the UV light as Shiba et al. teaches of the use of concave mirrors for the convergence of light and Shi et al. teaches of uniformly illuminating the semiconductor wafer with all of the UV light reflected by the UV reflector. The use of concave mirrors is advantageous to generate the desired effect, such as converging all of the UV light to provide for the uniform illumination of the semiconductor wafer and none of the extraneous UV radiation is lost.

48. Suzuki et al. does not disclose a protective housing and a bench for mounting.

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49. Maag et al. (US 6,472,026B1) discloses that UV lamps need a screen or an appropriately lined protective housing around the lamp unit to prevent radiation leakage from UV lamps (column 7, lines 32-52).

50. Gadgil et al. (5,780,860) discloses that a protective housing is used to prevent the accidental direct exposure of UV light to a user and thus assure their safety (column 5, lines 7-12).

51. At the time of the invention it would have been obvious to one ordinarily skilled in the art to provide a protective housing around the UV lamp of Suzuki et al. to prevent radiation leakage or direct exposure of UV light and thus assure the safety of the user of the UV device.

52. At the time of the invention it would have been obvious to one ordinarily skilled in the art that the UV apparatus of the combined disclosures is predictably mounted to a bench so that the apparatus is at waist height of the user and thus, provide ease of use as it would be uncomfortable and dangerous to have to bend down or reach up high to use.

Conclusion

53. No claims are allowed at this time.

54. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 7-4 M, 7-4 T, 6 Th, 7-4 F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa Perreira/
Examiner, Art Unit 1618